REMARKS

Entry of the foregoing amendments, favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the amendments and the following remarks.

Rejections under 35 U.S.C. § 103

In the Office Action, beginning at page 3, Claims 1-29 were rejected under 35 U.S.C. § 103(a) as reciting subject matters which are allegedly obvious, and therefore allegedly unpatentable, over certain documents. Specifically, Claim 25 was rejected over U.S. Patent No. 3,576,33, issued to Lee et al ("Lee"), and alternatively over U.S. Patent No. 4,868,866, issued to Williams, Jr. ("Williams"). Claims 1-24 and 26-29 were rejected over a document entitled "JetForm® Announces First Java™-Based Electronic Forms Solution" ("JetForm") in view of *Williams*. Applicants respectfully request reconsideration of these rejections.

Applicants first note that, while they strongly disagree with the negative patentability characterizations contained in the Office Action, each of the independent claims herein have been amended to recite combinations of steps or elements which are yet further patentable over the prior art. Claim 10 has been canceled, as its subject matter has been incorporated into Claim 1. Applicants amend the previously pending claims without disclaimer of or prejudice to the subject matters previously claimed.

Papers previously filed in this application have adequately described features of the present invention, and therefore no further, and possibly redundant, summaries will be given here so as not to burden the record.

Claim 1 relates to a computer-based method having a combination of steps including, *inter alia*, obtaining data from a clinical trial, receiving the data with a remote site computer, checking the data for validity, transmitting the data to a centralized computer, and receiving and validating the data at the centralized computer.

Claim 11 relates to a computer-based system having a combination of elements including, *inter alia*, first verification means and second verification means, wherein at least one of the first verification means and the second verification means comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

Claim 23 relates to a computer system for clinical trial management having a combination of elements including, *inter alia*, a first verification module and a second verification module, wherein at least one of the first verification module and the second verification module comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

Claim 25 relates to an article of manufacture comprising a computer program product having a combination of elements including a computer program product, the computer program product comprising means for causing a computer to provide a real-time computer based method for clinical trial data management using a centralized collection of geographically distribution information and means for checking the integrity of the stored clinical trial information.

Claim 28 relates to a method for use in clinical trial research having a combination of steps including, *inter alia*, obtaining data from a clinical trial, receiving the data from at least one user with a remote site computer, transmitting the data to a centralized computer, and providing physicians real time access to valid data in a central database at the centralized computer.

Claim 29 relates to a clinical trial management system having a combination of elements including, *inter alia*, first verification means at a remote site for verifying information for accuracy as the information is being entered with input means, second verification means at an information center for verifying the information received from the remote site input means by comparing the information with information previously stored at the information center, and wherein at least one of the first verification means and the second verification means comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

Applicants respectfully submit that all of the pending claims are patentable, for at least the following reasons.

Lee describes an electronic data entry verification system allegedly useful in automating a reordering process for large volume retailers, such as supermarkets and wholesalers. A "conventional adding machine" (col. 1, line 59) is modified in the *Lee* system for data input and rudimentary error detection, so that data transferred to magnetic storage, and ultimately to a wholesaler, is allegedly error-free. The data is, according to *Lee*, transferred to the wholesaler's computer via a modem, from which a paper copy of the order is printed. While *Lee* provides some detail about the structure and intended function(s) of his system, *Lee* fails to describe the collection of data at the wholesaler's site, e.g., by the wholesaler's computer. Indeed, *Lee* indicates that the wholesaler's computer prints out a paper copy of the order, suggesting that the data received by the wholesaler's computer is thereafter discarded. See, e.g., col. 2, lines 17-29. Furthermore, *Lee* is silent concerning the applicability of his system to clinical trials and/or clinical trial data.

Williams describes a financial data broadcast or distribution system. As appropriately noted in the Office Action, *Williams* fails to describe any use for his system other than for distributing financial data to 'subscribers' at certain subscription levels. *Williams* describes the collection of data from a number of diverse sources, such as securities exchanges, updating a central database with this data, and distributing various forms of the data to 'subscribers' based on their 'entitlement' to the data. *Williams* emphasizes that an object of his invention is to control access to broadcast data without the need for two-way communications between the subscribers and the central database. Col. 2, lines 35-39. *Williams* is silent concerning the applicability of his system to clinical trials and/or clinical trial data.

JetForm describes a JAVA-compliant electronic-forms tool or package. While *JetForm* describes general JAVA-based forms systems usable in intranet or internet environments, it is silent concerning the applicability of the system to clinical trials and/or clinical trial data. Indeed, *JetForm* suggests applicability to "remote field offices, customers, or even vendors", and fails to identify the applicability or desirability of using its system in clinical trials and/or with clinical trial data.

As noted above, there are numerous deficiencies in each of *Lee*, *Williams*, and *JetForms* with respect to the subject matters of the pending claims. In an apparent attempt to make up for one of the inadequacies of the prior art disclosures, the Office Action alleges that

"clinical trial data management is known in the art". See paragraph 8, lines 2-3 and paragraph 12, lines 2-3. Applicants strongly contest this allegation. The Office Action cites no evidence in the record to support this contention, which Applicants take as a clear indication that the prior art, at the time of Applicants invention, did not recognize any desirability in manipulating clinical trials and/or clinical trial data. Stated somewhat differently, the prior art is silent about clinical trials and/or clinical trial data because it was then not recognized that systems and methods such as those recited in the combinations of the pending claims should be used. The plain reason why the Office Action can point to no relevant prior art document which described clinical trials and/or clinical trial data, and which might provide the missing motivation to modify *Lee*, *Williams*, and *JetForm* in the manner alleged to be obvious in the Office Action, is that there are none which are prior art to the present claims.

Lacking such a specific document or other form of prior art evidence, and unless the patent examiner has specific and personal knowledge (see 37 C.F.R. § 1.104(d)(2)), Applicants respectfully submit that the various rejections of the claims are not supported by a *prima facie* case, and are therefore improper.

For at least the foregoing reasons, Applicants respectfully submit that Claims 1-9 and 11-29, each taken as a whole, patentably defines over the prior art. Applicants therefore respectfully request withdrawal of the rejections of Claims 1-9 and 11-29 under 35 U.S.C. § 103(a).

New Claims

Claims 30-32 have been added. Claim 30 depends from Claim 11, and Claim 32 depends from Claim 29; both claims further recite that both of the first verification means and the second verification means comprise means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable. Claim 31 depends from Claim 23, and further recites that both of the first verification module and the second verification module comprise means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable. Claims 30-32 are patentable for at least the same reasons as Claims 1-9 and 11-29, *supra*. Furthermore, Claims 30-32 are additionally patentable because the prior art fails to disclose, describe, or suggest the combinations of elements recited in each claim.

For at least the foregoing reasons, Applicants respectfully submits that Claims 30-32 are in condition for allowance.

Conclusion

For at least the foregoing reasons, Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of the present patent application is therefore respectfully solicited.

If Mr. Choules believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to Deposit Account No. 50-0622.

Respectfully submitted,

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Date: July 8, 2002

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1. (Amended) A computer-based method for centralized collection of geographically distributed information from at least one user at a remote site computer, comprising:

obtaining data from a clinical trial;

receiving said clinical trial data from the at least one user with the remote site computer;

checking the data for validity with the remote site computer;

providing the user an opportunity to correct any invalid data found during the checking;

transmitting the data to a centralized computer over a transmission medium;

receiving and validating the data from the remote site computer at the centralized computer, including comparing the data to data already stored at the centralized computer to determine if it is valid or invalid;

if the data from the remote site computer is determined to be invalid, then performing the following until all data is determined to be valid:

signaling with the centralized computer to the remote site computer to provide the user an opportunity to correct invalid data;

transmitting corrected data from the remote site computer to the centralized computer; and

receiving and validating the corrected data from the remote site computer at the centralized computer, including comparing the corrected data to data already stored at the centralized computer to determine if the data is valid or invalid;

when all data has been determined to be valid, then entering and storing the valid data in a central database at the centralized computer.

Claim 10 has been canceled.

11. (Amended) A computer-based system to gather, transmit, and store geographically distributed information comprising:

input means for entry of information at a remote site;

an information center having receiving means for receiving and storing the

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information;

transmission means for transmitting the entered information to the receiving means from the remote site input means;

first verification means at the remote site for verifying the information for accuracy as the information is being entered with the input means; [and]

second verification means at the information center for verifying the information received from the remote site input means by comparing the information with information previously stored at the information center;

wherein at least one of the first verification means and the second verification means comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

23. (Twice Amended) A computer system for clinical trial management of centralized collection of geographically distributed information, comprising:

a remote site computer having a browser with a first data verification module for verifying data entered at the remote site computer;

a transmission medium coupled to the remote site computer; and

a central computer coupled to the transmission medium, and having a database and a second data verification module for verifying data received from the remote site computer;

wherein at least one of the first verification module and the second verification module comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.

25. (Twice Amended) An article of manufacture comprising:

a computer program product, the computer program product comprising [mean] means for causing a computer to provide a real-time computer based method for clinical trial data management using a centralized collection of geographically distribution information [, further comprising] ; and

means for checking the integrity of the stored clinical trial information.

28. (Amended) An interactive computer web-enabled method for use in clinical

trial research using centralized collection of geographically distributed information from at least one user at a remote site computer, comprising:

obtaining data from a clinical trial;

receiving said data from the at least one user with the remote site computer;

checking the data for validity with the remote site computer;

providing the user an opportunity to correct any invalid data found during the checking;

transmitting the data to a centralized computer over a transmission medium;

receiving and validating the data from the remote site computer at the centralized computer, including comparing the data to data already stored at the centralized computer to determine if it is valid or invalid;

if the data from the remote site computer is determined to be invalid, then performing the following until all data is determined to be valid:

signaling with the centralized computer to the remote site computer to provide the user an opportunity to correct invalid data;

transmitting corrected data from the remote site computer to the centralized computer; and

receiving and validating the corrected data from the remote site computer at the centralized computer, including comparing the corrected data to data already stored at the centralized computer to determine if the data is valid or invalid;

when all data has been determined to be valid, then entering, storing, and providing physicians real time access to the valid data in a central database at the centralized computer to allow them to react quickly to the patient's symptoms.

29. (Amended) A web-enabled clinical trial management system for gathering, transmitting, and storing geographically distributed information comprising:

input means for entry of information at a remote site;

an information center having receiving means for receiving and storing information;

transmission means for transmitting the entered information to the receiving means from the remote site input means;

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first verification means at the remote site for verifying the information for accuracy as the information is being entered with the input means; and

second verification means at the information center for verifying the information received from the remote site input means by comparing the information with information previously stored at the information center;

wherein at least one of the first verification means and the second verification means comprises means for verifying the information for accuracy as clinical trial data against a predetermined clinical trial data variable.